REMARKS

This response is submitted in reply to the Office Action dated May 25, 2007 ("the Action"). Claims 1-29 and 34-73 are pending in the application. Claims 8, 10-12, 27, 53-55 and 70 have been withdrawn from consideration. The remaining pending claims stand rejected under 35 USC §112, first paragraph, for allegedly failing to comply with the written description requirement. Applicant respectfully disagrees.

More particularly, the Action states that the claims contain subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor at the time of the filing, had possession of the claimed invention. The Action cites the limitations "devoid of internal reinforcing material" and "devoid of endplates" as not being taught or suggested by the original disclosure. The Action then states that "the Applicant actually describes and claims embodiments having internal reinforcing material", citing to paragraphs 46, 51 and 54 and Claim 59 and endplates, citing to paragraph 53 and Claim 73. Again, Applicant respectfully disagrees and submits that the subject matter of the claim need not be described literally in order to satisfy the written description requirement.

A. Internal Reinforcing Material

Notably, contrary to the Action's assertion otherwise, paragraph 46 does not teach or suggest the use of any reinforcing material and provides written support for a molded device made of a single solid elastomeric material. Paragraph 46 (Example 1) describes the molding process used to generate a single solid elastomeric material implant. Paragraph 46 is restated below for ease of discussion.

> [0046] A preferred hydrogel for use in the practice of this invention is highly hydrolyzed crystalline poly (vinyl alcohol) (PVA). PVA cryogels may be prepared, from commercially available PVA powders, by any of the methods known to the art. Preferably, they are prepared by the method disclosed in U.S. Pat. Nos. 5,981,826 and 6,231,605, the teachings of which are incorporated herein by reference. Typically, 25 to 50% (by weight) PVA powder is mixed with a solvent, such as water. The mixture is then heated at a

> temperature of about 100 degrees Celsius (C) until a viscous solution is formed. The solution is then poured or injected into a metal or plastic mold such as shown in FIG. 1. The device is allowed to cool to below -10 degree C., preferably to about -20 degree C. The device is frozen and thawed several times until a solid device is formed with the desired mechanical properties. The device can them be partially or completely dehydrated for implantation. **The resulting prosthesis** has a mechanical elasticity of 2 MPa and has a mechanical ultimate strength in tension and compression of at least 1 MPa, preferably about 10 MPa. The prosthesis made by this method allows for 10 degrees of rotation between the top and bottom faces with torsions greater than 1 N-m without failing. The device thus made does not fracture when subjected to the same load constraints as the natural intervertebral disc. The device is a thus made of **a single solid elastomeric material** that is biocompatible by cytotoxicity and sensitivity testing specified by ISO (ISO 10993-5 1999: Biological evaluation of medical devices--Part 5: Tests for in vitro (italics) cytotoxicity and ISO 10993-10 2002: Biological Evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity.).

Emphasis added. Applicant respectfully submits that at least this paragraph describes molding an implant without internal reinforcing material.

It is true that Example 4 (paragraph 51) of the instant patent application states that an embedded internal spring(s) can be used to exert an expansion force to increase the height of the device. However, this is merely one example of one embodiment and is not described with respect to paragraph 46.

At paragraph 48, Example 2, the specification states that the body of the prosthesis may be reinforced with "fibers of polyethylene, polyglycolic acid, poly-paraphenylene terephthalamide, or silk, which are arranged in a circumferential direction, preferably as a complete woven mesh ring within the body of the device, or a crossing structure similar to the natural disc annulus." This is clearly described as an optional feature, so the reverse is also true: the device can be configured without such a feature. Also, at paragraph 50, Example 3, the specification states that:

> the device may be fabricated with different percentage weights of PVA at different stages of the molding process to yield a range of mechanical modulus of elasticity within the prosthetic spinal disc such that

> the elasticity is not constant. Similarly, two elastomers may be combined to yield elasticities that are not constant. Another approach can be to combine fibers or meshes within the device to yield anisotropic elasticity.

Both of these different Examples employ the word "may," indicating such a feature is optional; also, these features are discussed with respect to a different example (not Example 1). Indeed, even at paragraph 50, the Example states that there are two different ways to provide the anisotropic elasticity -- one clearly not requiring reinforcing material.

The Action alleges that paragraph 54 and Claim 59 also describe and claim the use of internal reinforcing material. However, paragraph 54 describes the use of appendages to allow immediate fixation *in situ*.

> [0054] The device may have an appendage to allow for immediate fixation in situ. For example, a prosthesis can be made to provide a screw anchor point for fixation in the vertebral body as shown in FIG. 4. Such a device can be made from a cryogel with elasticity between 0.2 and 5 megaPascals with tab extensions. The fixation appendages may extend from the main body of the spinal disc replacement. The elastomer is further surrounded along the circumference of the disc by a material that contains a ring of continuous fiber connected to the fixation appendage labeled as 12.

Clearly, paragraph 54 describes fixation appendages and does not describe internal reinforcing material for the molded body. Claim 59 has been amended to clarify that the material is molded to the disc body to provide the fixation appendages.

Thus, in summary, Applicant respectfully submits that at least Example 1 and the figures support that the implant is a single solid (monolithic) material which as molded provides sufficient written description of the lack of internal reinforcing material that provides the desired mechanical parameters without any such use of internal reinforcing material. While Applicant continues to believe that the recitation is supported by the original disclosure, Claim 43, which includes the recitation "consisting essentially of PVA," has been amended to remove the internal reinforcement material recitation.

B. Rigid Endplates

It is also true that Example 5, paragraph 53 of the instant application states, with respect to fibrosis, that metal solid or mesh can be used. However, Example 5 is directed to promoting "adhesion" to vertebral bodies by incorporating surface modifications. *See, e.g.*, paragraph 52 of Example 5. Example 5 also lists a number of options including polyester fabric and rough surfaces to provide cellular ingrowth. Clearly, just because one example states that metal can be used as a surface modification does not mean that rigid endplates are used with the implant, much less required, particularly in light of the complete lack of description at any other location and in view of the other examples and the figures which clearly illustrate that the implant does NOT include such a feature. Indeed, all of the figures support the claim recitation, *e.g.*, the lack of rigid endplates as the implant body **10** clearly does not have rigid endplates and is a single piece body **10** (**Figures 1-9**).

As is well-known, other spinal implants have used articulating metal rigid endplates that attach to local vertebral bone, sometimes sandwiching an interior component, rather than the implant configuration without endplates as shown in the figures. This lack of rigid endplate feature was discussed in the personal interview with the Examiner on July 7, 2006. This terminology was suggested by the Examiner in lieu of a "unitary body" structural recitation to describe the one-piece single solid implant shape. The Examiner is invited to suggest alternative terminology for this configuration MPEP 2163.

The Action also states that Claim 73 recites "endplates", but this claim recites a fabric molded to the solid body, wherein, in position, the fabric is affixed to vertebral bone. The fabric is not a rigid endplate.

Applicant respectfully submits that the "devoid of rigid endplates" feature is clearly shown in the figures and that the specification also supports the Applicant's position that the inventor was in possession of the invention at the time of filing the application.

C. Other Claim Recitations

The Action also objects to the use of certain claim terminology and alleges that other features in the claims are not supported by the specification as filed.

About

While Applicant disagrees that the use of the word "about" makes the claims vague, Applicant has amended Claims 4, 29, 53, 64 and 65 (and 63, 66 and 67) to remove the word "about" to advance prosecution.

Claim 10

The Action states that the range recited in Claim 10 is not found in the original disclosure. Claim 10 states that the delivered size of the prosthesis can expand at least 5% in at least one dimension in vivo without injection of material. Paragraph 51 states that the prosthesis can swell from 5% to 600% over 24 hours when placed in saline. Further, original Claim 9 recites the 5% range and Applicant respectfully submits that this range is supported by at least original presentation of the claimed subject matter (*see,* MPEP 2163.03).

Claim 34

The Action states that the pair of ranges in Claim 34 is not supported by the original disclosure. Applicant has amended Claim 34 to correspond to the pair of ranges in original Claim 1 (and amended dependent Claim 42 to recite the larger values of Example 1).

Claim 35

The Action states that the recitation "the fabric mesh molded *only* to exterior surfaces" of the hydrogel is not discussed in the original disclosure. First, Applicant directs the Examiner's attention to Figure 4, which shows an extension member attached to the outer surface of the implant body. Example 7 also describes that fabric is molded into the device near the circumferential, cranial and caudal surfaces and that the fabric can extend beyond the body of the device as fabric appendages used to attach to sides of vertebrae. Paragraph 25 also states that the device can have extensions from the faces or circumference of the device to allow for surgical fixation to vertebral bodies. In addition, original Claims 13-15 (supported at least by original presentation) recite the surface modification is a fabric or mesh.

In order to advance prosecution, Applicant has amended Claim 35 to recite that the fabric mesh is molded to the disc body and extends beyond the body to define fixation appendages.

Claim 47

The Action alleges that the *monolithic* body of freeze-thaw cryogel that defines a core *and* annulus is not taught by the original disclosure. Again, Applicant resepctfully disagrees. Further, the term "monolithic" was suggested by the Examiner during the interview of July 7, 2006 as an alternative to the word "unitary" to claim the single piece body. As in some embodiments, the molded body is solid and uniform throughout, the term "monolithic" was suggested as a better term for that configuration. Applicant also submits that at least Example 1 clearly describes the monolithic (single material and unitary body) solid freeze-thaw molded body and cites to Figure 1. Figures 1-4 clearly show the molded freeze-thaw body is a single body that forms both the annulus and core.

The word "monolithic" is also recited in Claims 26, 29 and 40. Applicant respectfully invites the Examiner to suggest alternative terminology per MPEP 2163 if he still objects to the use of the word "monolithic".

Claims 10, 54, 66 and 69

The Action states that the "further limitations" of Claims 10, 54, 66 and 69 are unsupported in the original disclosures. Claim 10 was discussed above and has been amended to correspond to original Claim 9. Claims 54 and 66 have been amended to more clearly correspond to the written text at paragraph 51. Claim 69 has been amended recite a band member attached to a circumferential surface thereof (paragraph 40) rather than a sleeve to more clearly correspond to the text.

Request for Interview

Applicant sincerely wishes to overcome the written description rejections and arrive at suitable claim terminology. If the Examiner remains unpersuaded by the above statements, Applicant respectfully requests an Interview to discuss resolution of these issues.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. The Examiner is encouraged to telephone the undersigned at 919-854-1400 for resolution of any outstanding issues.

Respectfully submitted,

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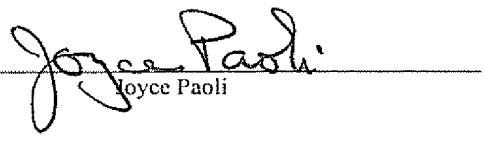
Signature: 
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